FEB - 3 2014

5. 510(k) Summary

Table 5-1 510(k) Summary Table	
Submitter:	I-Flow, LLC 43 Discovery, Suite 100 Irvine, CA 92618
Contact:	Shelly Harris Regulatory Affairs Manager I-Flow, LLC Tel: (949) 923-2400 Fax: (949) 923-2401 Email: shelly.harris@kcc.com
Trade Names:	ON-Q Pain Relief System, ON-Q PainBuster, ON-Q C-bloc, Homepump C-Series and Homepump Eclipse
Common Name:	Elastomeric Infusion Pump
Existing / Predicate Devices:	I-Flow Elastomeric Pump K063530 K052117
Device Changes:	This Traditional 510(k) submission proposes the following changes to incorporate: Use a *single* Silicone bladder for the elastomeric pump. The predicate elastomeric pump consists of a *dual* Kraton (inner) and Latex (outer) bladder design configuration. Components will not be manufactured or formulated with DEHP as a plasticizer. For the low flow (i.e., 0.5 – 10 ml/hr) elastomeric pump models, the filter pore size was reduced from 1.2 micron to 0.22 micron to further enhance the elimination of particulate matter and air bubbles from the device.

K131249

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	Trade Name	**ON-Q Pain Relief System/ON-Q PainBuster**	**ON-Q C bloc**	**Homepump Eclipse**	**Homepump C-Series**
Device Description:	**Target Market**	Regional analgesia and anesthesia		Home infusion	
	Primary Application	Surgical Site or Nerve Block		Antibiotics	Chemotherapy
	Device Description	The I-Flow Silicone/Non-DEHP Elastomeric Pumps consist of an elastomeric pressure source with an integrated administration set. The elastomeric membrane functions as the fluid reservoir and the pressure source. The desired flow rate is regulated by a restrictor orifice or fixed flow tubing that controls flow generated by the pressurized bladder. The pre-attached administration set may incorporate any of the following components: • Y-tubing for multi-site delivery (single or dual) • Air and particulate eliminating filter • Flow Restrictor • Luer Connector The pump may be sold as a kit with additional devices or accessories such as the following: catheter, introducer needle, syringe, and E-clip.			
	Approx. Deliver Times	1 - 5 days		15 min – 5 hrs	8 days
Indication for Use:	The I-Flow Elastomeric Pump is intended for infusion of medications including antibiotic delivery, chemotherapy and pain management. Routes of administration include intravenous, subcutaneous and epidural. The I-Flow Elastomeric Pump is also intended for infusion of medication (such as local anesthetics or narcotics) for local or regional anesthesia and pain management. Routes of administration include: perineural (nerve block), into intraoperative sites (infiltration), percutaneous and epidural. The I-Flow Elastomeric Pump is also intended to significantly decrease narcotic use and pain when used to deliver local anesthetics to or around surgical wound sites or close proximity to nerves when compared with narcotic-only pain management. The indications for use include hospital, alternate care, ambulatory and home environments.				

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Technology Comparison:	There is no change in fundamental scientific technology or principles of operation. The design remains the same as the predicate devices. All the non-clinical data and tests (i.e., flow rate accuracy, fill/crack pressure, residual volume, pump integrity, biocompatibility, chemical characterization, drug compatibility) performed, met the design requirements and acceptance criteria, thereby demonstrating substantial equivalence to the predicate devices.		
	Technology Characteristics	**Predicate Devices**	**New Pump**
	Drug reservoir material	Dual bladder: Latex Outer bladder Kraton Inner bladder (fluid contact)	Single bladder: Single layer silicone
	Administration set	Di(2-ethylhexhyl) phthalate (DEHP) Plasticized Polyvinyl Chloride (PVC)	Trioctyl Trimellitate (TOTM) plasticized PVC
	Bag, 100ml ON-Q, Radio Frequency (RF) Seal w/Vent (non-fluid path)	DEHP plasticized PVC	Di(2-ethylhexyl) terephthalate (DEHT) plasticizer PVC
	Inline Filter	1.2 micron size filter, air eliminating	0.22 micron, air-eliminating filter
Performance Data	Testing of the I-Flow Silicone/Non-DEHP Elastomeric Pump was conducted, including performance, biocompatibility, and chemical characterization testing. A Clinical Evaluation was determined not to be required; however, a simulated use study of human factors was conducted with intended users in the intended use environment that evaluated device performance, possible use error and user perception of difficulties with pump use. The study assessed the critical tasks or use scenarios where use related errors are most likely to occur. A Safety Case and Hazard Analysis demonstrated an acceptable risk profile based on design-based risk mitigation and satisfactory performance testing. Results of design verification and validation testing demonstrated that the I-Flow Silicon/Non-DEHP Elastomeric Pump functions as designed and can be operated by the user as intended through the user interface and instuctions provided.		

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Conclusion:	The *I-Flow Elastomeric Pumps* are as safe and effective and perform as well as the predicate devices.
Date Summary Prepared:	January 31, 2013

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 3, 2014

Shelly Harris
Regulatory Affairs Manager
I-Flow, LLC
20202 Windrow Drive
Lake Forest, California 92630

Re: K131249
Trade/Device Name: I-Flow Elastomeric Pump
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: MEB
Dated: December 31, 2013
Received: January 2, 2014

Dear Ms. Harris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer for
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Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K131249

Device Name
I-Flow Elastomeric Pump

Indications for Use *(Describe)*
The I-Flow Elastomeric Pump is intended for infusion of medications including antibiotic delivery, chemotherapy, and pain management. Routes of administration include intravenous, subcutaneous, and epidural.

The I-Flow Elastomeric Pump is also intended for infusion of medication (such as local anesthetics or narcotics) for local or regional anesthesia and pain management. Routes of administration include: perineural (nerve block), into interoperative sites (infiltration), percutaneous and epidural.

The I-Flow Elastomeric Pump is also intended to significantly decrease narcotic use and pain when used to deliver local anesthetics to or around surgical wound sites or close proximity to nerves when compared to narcotic-only pain management.

The indications for use include hospital, alternate care, ambulatory and home environments.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FDA

Digitally signed by Richard C. Chapman
Date: 2014.02.03 15:14:28 -05'00'

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